WE CLAIM:

1. A controlled release oral solid dosage form for the reduction of serum cholesterol levels in humans comprising a drug comprising an alkyl ester of hydroxy substituted naphthalenes and a controlled release carrier in an amount effective to provide a controlled release of the drug, the dosage form providing a mean time to maximum plasma concentration (T_{max}) of the drug which occurs at about 10 to about 32 hours after oral administration to human patients, the dosage form providing a reduction in serum cholesterol levels when administered to human patients on a once-a-day basis.

2. The controlled release oral solid dosage form of claim 1, which includes an amount of a controlled release carrier for said drug effective to provide a substantially complete release of said drug in about 4 to 30 hours in vitro in a Type 2 USP 23 dissolution apparatus in 2% sodium lauryl sulfate, pH buffer to 7.0 at 37°C and 50rpm.

3. The controlled release oral solid dosage form of claim 1, which provides a dissolution of from about 0% to about 25% drug released after 2 hours; from about 40% to about 85% drug released after 6 hours; and not less than about 75% drug released after 16 hours, when measured in vitro in a Type 2 USP 23 dissolution apparatus in 2% sodium lauryl sulfate, pH buffer to 7.0 at 37°C and 50rpm.

4. The controlled release oral solid dosage form of claim 1, which provides a dissolution of from about 0% to about 20% drug released after 2 hours; from about 50% to about 80% drug released after 6 hours; and not less than about 80% drug released after 16 hours, when measured in vitro in a Type 2 USP 23 dissolution apparatus in 2% sodium lauryl sulfate, pH buffer to 7.0 at 37°C and 50rpm.

5. The controlled release oral solid dosage form of claim 1, which provides a dissolution of from about 10% to about 15% drug released after 2 hours; from about 65% to about 75% drug released after 6 hours; and not less than about 79% drug released after 16 hours,

when measured in vitro in a Type 2 USP 23 dissolution apparatus in 2% sodium lauryl sulfate, pH buffer to 7.0 at 37°C and 50rpm.

6. The controlled release oral solid dosage form of claim 1, which provides a mean time to maximum plasma concentration about 14 to about 24 hours after oral administration.

7. The controlled release dosage form of claim 1, wherein the drug is lovastatin, said dosage form providing a mean maximum plasma concentration (C_{max}) of lovastatin from about 1 ng/ml to about 8 ng/ml, based on a 40 mg dose of lovastatin, after administration to human patients.

8. The controlled release dosage form of claim 1, wherein the drug is lovastatin, said dosage form providing a maximum plasma concentration (C_{max}) of the drug of from about 3 ng/ml to about 4 ng/ml (based on a 40 mg dose of lovastatin), after administration to human patients.

9. The controlled release dosage form of claim 1, wherein the drug is selected from the group consisting of lovastatin, a derivative of lovastatin, an active metabolite of lovastatin, mevastatin, pravastatin, simvastatin, and mixtures thereof.

10. The controlled release dosage form of claim 1, wherein the drug is lovastatin.

11. The controlled release dosage form of claim 1, wherein the drug is lovastatin in an amount of from about 10 to about 80 mg.

12. The controlled release dosage form of claim 1, wherein the drug is lovastatin, and the dosage form provides a mean AUC_{0-48hr} of lovastatin from about 15 to about 90 ng•hr/ml.

13. The controlled release dosage form of claim 1, wherein the drug is lovastatin, and the dosage form provides a mean AUC_{0-48hr} of lovastatin from about 34 to about 77 ng•hr/ml.

14. The controlled release dosage form of claim 1, wherein the drug is lovastatin and the dosage form provides a mean time to maximum plasma concentration of lovastatin acid at about 5.3 to about 28.7 hours after oral administration.

15. The controlled release dosage form of claim 1, wherein the drug is lovastatin and the dosage form provides a mean time to maximum plasma concentration of lovastatin acid at about 13.0 to about 20.9 hours after oral administration.

16. The controlled release dosage form of claim 1, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of lovastatin acid from about 1.05 ng/ml to about 7.22 ng/ml, based on a 40 mg dose of lovastatin.

17. The controlled release dosage form of claim 1, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of lovastatin acid from about 2.50 ng/ml to about 4.90 ng/ml, based on a 40 mg dose of lovastatin.

18. The controlled release dosage form of claim 1, wherein the drug is lovastatin and the dosage form provides a mean AUC_{0-48hr} of lovastatin acid from about 9.96 to about 132.54 ng•hr/ml.

19. The controlled release dosage form of claim 1, wherein the drug is lovastatin and the dosage form provides a mean AUC_{0-48hr} of lovastatin acid from about 47.5 to about 91.2 ng•hr/ml.

20. The controlled release dosage form of claim 1, which provides a mean time to maximum plasma concentration of total HMG-CoA Reductase Inhibitors at about 13 to about 21 hours after oral administration.

21. The controlled release dosage form of claim 20, which provides a mean maximum plasma concentration (C_{max}) of total HMG-CoA Reductase Inhibitors from about 4.7 ng/ml to about 25.4 ng/ml, based on a 40 mg dose of lovastatin.

22. The controlled release dosage form of claim 20, which provides a mean maximum plasma concentration (C_{max}) of total HMG-CoA Reductase Inhibitors from about 10.5 ng/ml to about 17.3 ng/ml, based on a 40 mg dose of lovastatin.

23. The controlled release dosage form of claim 1, which provides a mean time to maximum plasma concentration of active HMG-CoA Reductase Inhibitors at about 6.2 to about 20.1 hours after oral administration.

24. The controlled release dosage form of claim 1, which provides a mean time to maximum plasma concentration of active HMG-CoA Reductase Inhibitors at from about 9.5 to about 15.2 hours after oral administration.

25. The controlled release dosage form of claim 23, which provides a mean maximum plasma concentration (C_{max}) of active HMG-CoA Reductase Inhibitors from about 2.1 ng/ml to about 22.5 ng/ml, based on a 40 mg dose of lovastatin.

26. The controlled release dosage form of claim 23, which provides a mean maximum plasma concentration (C_{max}) of active HMG-CoA Reductase Inhibitors from about 6.4 ng/ml to about 13.4 ng/ml.

27. The controlled release oral solid dosage form of claim 1, which provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 11 to about 32 hours after oral administration of a single dose of said drug to human patients in the morning.

28. The controlled release oral solid dosage form of claim 27, wherein the dosage form provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 16

to about 32 hours after oral administration of a single dose after breakfast (in the fed state).

29. The controlled release oral solid dosage form of claim 28, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of the drug from about 1.5 ng/ml to about 4.5 ng/ml, based on a 40 mg dose of lovastatin, after oral administration of a single dose after breakfast (in the fed state).

30. The controlled release oral solid dosage form of claim 1, which when administered in the morning in the fasted state, provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 9 to about 13 hours after administration.

31. The controlled release oral solid dosage form of claim 1, which when administered in the morning in the fed state, provides a mean time to maximum plasma concentration (T_{max}) which occurs at from about 22 to about 26 hours after administration.

32. The controlled release dosage form of claim 1, wherein the drug is lovastatin, said dosage form providing a mean maximum plasma concentration (C_{max}) of lovastatin from about 1.5 ng/ml to about 7.1 ng/ml, based on a 40 mg dose of lovastatin, after administration to human patients.

33. The controlled release oral solid dosage form of claim 1, which provides a mean time to maximum plasma concentration (T_{max}) at about 10.4 to about 20.6 hours after oral administration to human patients after administration of a single dose of said drug at dinner time.

34. The controlled release oral solid dosage form of claim 33, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug from about 1.9 ng/ml to about 4.4 ng/ml, based on a 40 mg dose of lovastatin.

35. The controlled release oral solid dosage form of claim 33, which provides a mean time to maximum plasma concentration (T_{max}) at about 13.5 to about 17.5 hours after oral administration at dinner time.

36. The controlled release oral solid dosage form of claim 35, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of lovastatin of about 3 ng/ml, based on a 40 mg dose of lovastatin.

37. The controlled release oral solid dosage form of claim 1, which dosage form provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 10 to about 23.2 hours after oral administration to a human patient after administration of a single dose of said drug to human patients at bedtime.

38. The controlled release oral solid dosage form of claim 37, which dosage form provides a mean time to maximum plasma concentration (T_{max}) at about 14.2 to about 16.9 hours after oral administration of a single dose of said drug to human patients at bedtime.

39. The controlled release oral solid dosage form of claim 1, which dosage form provides a mean time to maximum plasma concentration (T_{max}) at about 10 to about 22 hours at steady-state after oral administration to human patients at bedtime.

40. The controlled release oral solid dosage form of claim 39, which dosage form provides a mean time to maximum plasma concentration (T_{max}) at about 12 to about 16 hours at steady-state after oral administration to human patients at bedtime.

41. The controlled release oral solid dosage form of claim 39, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug from about 1 ng/ml to about 8 ng/ml, based on a 40 mg dose of lovastatin.

42. The controlled release oral solid dosage form of claim 40, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of the drug

of about 4 ng/ml, based on a 40 mg dose of lovastatin, after oral administration of a single dose at bedtime.

43. The controlled release oral solid dosage form of claim 1, wherein the drug is selected from the group consisting of lovastatin, a derivative of lovastatin, an active metabolite of lovastatin, and mixtures thereof.

44. The controlled release oral solid dosage form of claim 3, which provides a mean time to maximum plasma concentration about 14 to about 24 hours after oral administration.

45. The controlled release dosage form of claim 44, wherein the drug is lovastatin, said dosage form providing a mean maximum plasma concentration (C_{max}) of lovastatin from about 1.5 ng/ml to about 7.1 ng/ml, based on a 40 mg dose of lovastatin, after administration to human patients.

46. The controlled release dosage form of claim 44, wherein the drug is lovastatin, said dosage form providing a maximum plasma concentration (C_{max}) of the drug of from about 3 ng/ml to about 4 ng/ml (based on a 40 mg dose of lovastatin), after administration to human patients.

47. The controlled release oral solid dosage form of claim 44, which achieves an accumulation of lovastatin and its latent and active metabolites at steady-state conditions of about 1.4- to about 2-fold the levels attained by immediate release lovastatin administered once daily.

48. A method for reducing serum cholesterol levels in humans, comprising orally administering a drug comprising an alkyl ester of hydroxy substituted naphthalenes in a controlled release oral solid dosage form which provides a mean time to maximum plasma concentration (T_{max}) of the drug which occurs at about 10 to about 32 hours after oral administration of said dosage form to human patients.

49. The method of claim 48, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of lovastatin from about 1 ng/ml to about 8 ng/ml, based on a 40 mg dose of lovastatin, after administration to human patients.

50. The method of claim 48, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of lovastatin from about 1.5 ng/ml to about 7.1 ng/ml, based on a 40 mg dose of lovastatin, after administration to human patients

51. A method for reducing serum cholesterol levels in humans, comprising orally administering a drug comprising an alkyl ester of hydroxy substituted naphthalenes in a controlled release oral solid dosage form to human patients in the morning, which dosage form provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 11 to about 32 hours after oral administration to human patients.

52. The method of claim 51, wherein the drug is lovastatin.

53. The method of claim 51, wherein the T_{max} occurs at about 16.3 to about 24 hours after administration.

54. The method of claim 51, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug from about 1.5 ng/ml to about 6.9 ng/ml, based on a 40 mg dose of lovastatin.

55. The method of claim 51, further comprising administering the dosage form in the morning in the fasted state, such that the dosage form provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 5.3 to about 17 hours after oral administration of a single dose, and a mean maximum plasma concentration (C_{max}) of the drug from about 2.9 ng/ml to about 6.9 ng/ml, based on a 40 mg dose of lovastatin, after oral administration of a single dose.

56. The method of claim 51, further comprising administering the dosage form in the morning in the fasted state, such that the dosage form provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 9 to about 13 hours after administration.

57. The method of claim 51, further comprising administering the dosage form in the morning in the fed state, such that the time to maximum plasma concentration (T_{max}) occurs from about 22 to about 26 hours after administration.

58. A method for reducing serum cholesterol levels in humans, comprising orally administering a drug comprising an alkyl ester of hydroxy substituted naphthalenes in a controlled release oral solid dosage form to human patients at dinner time, which dosage form provides a mean time to maximum plasma concentration (T_{max}) at about 10.4 to about 20.6 hours after oral administration of a single dose of lovastatin to a population of human patients.

59. The method of claim 58, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug from about 1.9 ng/ml to about 4.4 ng/ml, based on a 40 mg dose of lovastatin.

60. The method of claim 58, wherein the mean time to maximum plasma concentration (T_{max}) occurs at from about 13.5 hours to about 17.5 hours after oral administration.

61. The method of claim 60, wherein the drug is lovastatin, and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug of about 3 ng/ml, based on a 40 mg dose of lovastatin.

62. A method for reducing serum cholesterol levels in humans, comprising orally administering a drug comprising an alkyl ester of hydroxy substituted naphthalenes in a controlled release oral solid dosage form to human patients at bedtime, which dosage

form provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 10 to about 23.2 hours after oral administration.

63. The method of claim 62, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug from about 1 ng/ml to about 8 ng/ml, based on a 40 mg dose of lovastatin.

64. The method of claim 62, wherein the dosage form provides a mean time to maximum plasma concentration (T_{max}) which occurs at about 14.2 to about 16.9 hours after oral administration of a single dose.

65. The method of claim 62, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of the drug of about 4 ng/ml, based on a 40 mg dose of lovastatin, after oral administration of a single dose.

66. The method of claim 62, wherein said T_{max} occurs at about 10 to about 22 hours after oral administration to human patients at steady-state.

67. The method of claim 62, wherein said T_{max} occurs at about 12 to about 16 hours after oral administration.

68. The method of claim 66, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug from about 3 ng/ml to about 8 ng/ml, based on a 40 mg dose of lovastatin at steady-state.

69. The method of claim 66, wherein the drug is lovastatin and the dosage form provides a mean maximum plasma concentration (C_{max}) of said drug of about 5.5 ng/ml.

70. A method for improving the dose-response relationship achieved via the administration of a statin drug orally administered in immediate release form, comprising orally administering the statin in a controlled release dosage form which provides a mean time

to maximum plasma concentration (T_{max}) of the statin drug which occurs at about 10 to about 32 hours after oral administration to human patients.

71. A method for providing increased systemic bioavailability of lovastatin, while at the same time not increasing the bioavailability of lovastatin acid, active or total inhibitors compared to an immediate release reference standard form of lovastatin, comprising preparing a controlled release oral solid dosage form of lovastatin which comprises a therapeutically effective amount of lovastatin and a sufficient amount of a controlled release carrier such that the controlled release dosage form provides a dissolution of from about 0% to about 25% lovastatin released after 2 hours; from about 40% to about 85% lovastatin released after 6 hours; and not less than about 75% lovastatin released after 16 hours, when measured in vitro in a Type 2 USP 23 dissolution apparatus in 2% sodium lauryl sulfate, pH buffer to 7.0 at 37°C and 50rpm, and such that said dosage form provides a mean time to maximum plasma concentration (T_{max}) of said lovastatin from about 10 to about 32 hours after oral administration to human patients, and administering said dosage form to human patients on a once-a-day basis.

72. A controlled release oral solid dosage form, comprising a therapeutically effective amount of lovastatin, and a controlled release carrier providing delivery of said lovastatin when said dosage form is orally administered to human patients, such that a mean maximum plasma concentration (C_{max}) of lovastatin from about 1 ng/ml to about 5.5 ng/ml is attained, after administration of a single dose or at steady-state in a population of human patients in need of such therapy, per 40 mg dose of lovastatin.

73. The controlled release oral solid dosage form of claim 72, wherein said mean maximum plasma concentration (C_{max}) of lovastatin provided by said dosage form is from about 3 ng/ml to about 5.5 ng/ml.

74. A method for reducing serum cholesterol levels in humans, comprising orally administering a controlled release oral solid dosage form containing a therapeutically effective amount of lovastatin which provides a mean maximum plasma concentration

(C_{max}) of lovastatin from about 1 ng/ml to about 5.5 ng/ml after administration of a single dose or at steady-state in a population of human patients in need of such therapy, per 40 mg dose of lovastatin.

75. The method of claim 74, wherein said mean maximum plasma concentration (C_{max}) of lovastatin provided by said dosage form is from about 3 ng/ml to about 5.5 ng/ml.